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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,579	10/20/2003	Julio C. Palmaz	JOH2748P0044US	2120
32116	7590	03/09/2006	EXAMINER	
WOOD, PHILLIPS, KATZ, CLARK & MORTIMER 500 W. MADISON STREET SUITE 3800 CHICAGO, IL 60661			PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/689,579

Applicant(s)

PALMAZ ET AL.

Examiner

Paul B. Prebilic

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-36 is/are allowed.
- 6) ☒ Claim(s) 25,29,45 and 65 is/are rejected.
- 7) ☒ Claim(s) 37-44 and 46-64 is/are objected to.
- 8) ☐ Claim(s) are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. .
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u> </u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/14/05, 5/27/05</u> | 6) <input type="checkbox"/> Other: <u> </u> |

While there is concurrent litigation related to this reissue application, action in this reissue application will NOT be stayed because of applicant's request that the application be examined at this time. Due to the related litigation status of this reissue application, EXTENSIONS OF TIME UNDER THE PROVISIONS OF 37 CFR 1.136(a) WILL NOT BE PERMITTED.

The patent sought to be reissued by this application is involved in litigation. Any documents and/or materials which would be material to the patentability of this reissue application are required to be made of record in reply to this action.

Due to the related litigation status of this application, EXTENSIONS OF TIME UNDER THE PROVISIONS OF 37 CFR 1.136(a) WILL NOT BE PERMITTED DURING THE PROSECUTION OF THIS APPLICATION.

The certificate of correction of the patent was not entered as though it was part of the original patent; see MPEP 1411.01 that is incorporated herein by reference thereto.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the inventors did not sign it and the provisions of 37 USC 118 were not complied with; see MPEP 409.03 and 409.03(b) that are incorporated herein by reference. Applicant is directed to pay particular attention to items (A) to (F) if MPEP 409.03(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45 and 65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not provide an enabling disclosure for the terms "polyglycoides", "polylacoides", and "polylocoides" because these terms have no known meaning in the art; see the cited searches of these terms from Onelook.com, an internet website that searches numerous online dictionaries. For this reason, one could not make the claimed invention; see MPEP 2164.01(b).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As explained above, the terms "polyglycoides", "polylacoides", and "polylocoides" have no known meaning in the art, and for this reason, the claim language is considered indefinite.

Alternatively, if one were to consider the "oide" suffix as merely a broader manner to claim "polylactide" or "polyglycolide", the Examiner asserts that the claim language is indefinite in that the specification fails to provide some standard for

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measuring the degree of variation from the art accepted terminology. Therefore, one of ordinary skill would not know what degree of these terms that would fall within the claim scope and what would not. The controlling case law appears to be that of *In re Mattison*, 184 USPQ 383 (CCPA 1960). It states:

We are not persuaded by the board's reasoning that one skilled in the art would not be able to determine the scope of the claimed invention in terms of a specified percentage value. General guidelines are disclosed for a proper choice of the substituent Ep together with a representative number of examples. (emphasis added here)

The Board of Appeals was reversed because there were general guidelines as to what constituted a substantial increase. This is not the situation here where there are no guidelines in the specification, and the prior art does not give one a clear picture as to what constitutes a chemical compound within the claim scope and what does not. This is a critical and defining limitation of the claim and it must be clear as to what falls within its scope.

Claim Objections

Claims 37-65 are objected to because of the following informalities:

With regard to claim 37, lines 7-8, and claim 52, lines 8-9, "a drug that is released into the coronary artery at the site of implantation" appears to be a statement of intended use, and it therefore, confusing. In order to overcome this objection, the Examiner suggests changing "is released" to ---is capable of being released---. Claims 38-51 and 53-65 are also objected to since they depend upon the objected to base claims and contain the same objectionable language.

In claims 42, 44, 61 and 63, the “coating” already has a subcomponent from the base claim, and thus, the use of “comprising” thereafter is confusing because it is unclear whether more elements, or rather, replacement elements are being claimed. The Examiner suggests changing “comprising” to ---further comprising--- in order to overcome this objection.

In claim 52, line 16, “the stent prosthes~~is~~” lacks clear antecedent basis; the Examiner suggests using “the stent prostheses” in order to overcome this objection.

In claim 52, lines 16-17, “the stent prosthesis” lacks clear antecedent basis; the Examiner suggest changing it to ---the least one of the at least one stent prostheses--- in order to overcome this objection.

In claim 52, lines 18 and 19, there are two occurrences of using “the stent prosthesis” such that it lacks antecedent basis.

In claims 53 and 54, line 1 of each, “including” is confusing for the reasons explained above pertaining to the term “coating comprising.” The Examiner suggests changing “including” to ---further including--- in order to overcome this objection.

In claim 59, line 1, “the adjacent prosthesis” lacks antecedent basis.

Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: In claim 65, the term “polylocoides” lacks proper antecedent basis, but it may be a misspelling for the indefinite term “polylacoides.”

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25 and 29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4 of U.S. Patent No. 5,195,984. Although the conflicting claims are not identical, they are not patentably distinct from each other because present claims 25 and 29 are read on by patented claims 1 and 4, respectively, such that the present claims are anticipated thereby. For this reason, claims 25 and 29 are considered clearly obvious in view of claims 1 and 4.

Allowable Subject Matter

Claims 1 to 36 are allowed over the prior art of record.

Claims 36-44 and 46-64 are objected to but would be allowable if rewritten to eliminate the objectionable language.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738